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Docket: A. Corbin

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2004D–0187, 2004D–0188, and 2004D–0189]

Guidances for Industry on Premarketing Risk Assessment; Development and Use of Risk Minimization Action Plans; and Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of three guidances for industry entitled "Premarketing Risk Assessment," "Development and Use of Risk Minimization Action Plans," and "Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment." These guidances provide guidance to industry on risk management activities for drug products, including biological drug products, in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The guidances address, respectively, premarket risk assessment; the development, implementation, and evaluation of risk minimization action plans for drug products; and good pharmacovigilance practices and pharmacoepidemiologic assessment of observational data.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidances to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD

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20857, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. These guidances may also be obtained by mail by calling CBER at 1–800–4709 or 301–827–1800. Send three self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify each set of comments with the corresponding docket number of the guidance as follows: Docket No. [2004D–0187] "Premarketing Risk Assessment," Docket No. [2004D–0188] "Development and Use of Risk Minimization Action Plans," and Docket No. [2004D–0189] "Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment." See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance documents.

FOR FURTHER INFORMATION CONTACT: *For "Premarketing Risk Assessment"*: Barbara Gould, Center for Drug Evaluation and Research (HFD–550), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2504, or

Patricia Rohan, Center for Biologics Evaluation and Research (HFM–485), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3070.

For "Development and Use of Risk Minimization Action Plans": Christine Bechtel, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–443–5572, or

Mark Weinstein, Center for Biologics Evaluation and Research (HFM–300), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3518.

For "Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment": Patrick Guinn, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301–443–5590, or

Miles Braun, Center for Biologics Evaluation and Research (HFM–220), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of three guidances for industry entitled "Premarketing Risk Assessment," "Development and Use of Risk Minimization Action Plans," and "Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment." These three guidances were produced in part to fulfill FDA's commitment to certain risk management performance goals agreed to in relation to the Prescription Drug User Fee Act upon its reauthorization in June 2002. As an initial step, FDA announced the availability of three concept papers on March 7, 2003 (68 FR 11120). Each concept paper focused on one aspect of risk management. FDA held a public workshop on April 9 to 11, 2003, to obtain comment on the concept papers. The comments submitted on the concept papers and at the public meeting were considered in developing the draft guidances. The draft guidances were published on May 5, 2004 (69 FR 25130), and the public was provided with

an opportunity to comment on them until July 6, 2004. FDA considered all of the comments received in producing the final guidances.

The guidances address risk management issues pertinent to the successive stages of a product's lifecycle, specifically the following topics: (1) During medical product development, (2) during product application review and approval, and (3) during the postmarketing period. The approaches recommended in the guidances are part of a broad, ongoing, and comprehensive effort by the agency to provide additional guidance to industry on measures that can be employed to minimize the risks while preserving the benefits of medical products.

These guidances recommend that sponsors consider specific risk minimization efforts beyond routine risk minimization measures for the few products presenting unusual types or levels of risk. In these circumstances, using strategies that go beyond routine risk assessment and minimization may further improve the product's benefit-risk balance.

FDA understands that risk management programs generate costs and place new burdens on product developers, health care practitioners, and patients. FDA recommends that, whenever possible, sponsors give every consideration to using the least burdensome method to achieve the desired public health outcome.

FDA recommends that as new products are developed, sponsors seek to identify risk signals as early as possible in a product's development cycle, to evaluate the risks, to communicate predictable risk and benefit information effectively and thoroughly, and to employ efforts to manage these risks as efficiently as possible.

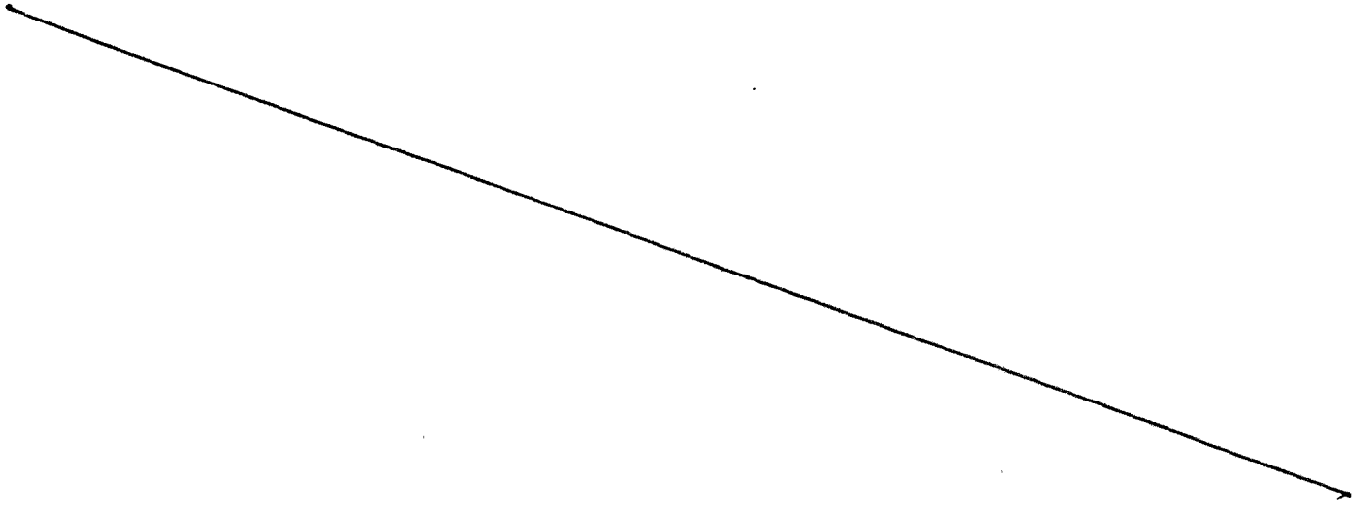
These guidances are being issued consistent with FDA's good guidances practices regulation (21 CFR 10.115). The guidances represent the agency's current thinking on this topic. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written comments on the guidances at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket numbers found in brackets in the heading of this document. The guidances and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

These guidances contain information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection(s) of information in the guidances were approved under OMB control numbers 0910–0001 (until March 31, 2005) and 0910–0338 (until August 31, 2005).



IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: 3/24/05

March 24, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

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